UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,220	03/22/2004	Kazunari Yamaguchi	Q80490	9623

23373 7590 01/15/2009

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
01/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.**	**Applicant(s)**	
	10/805,220	YAMAGUCHI ET AL.	
	Examiner	**Art Unit**	
	Stacy B. Chen	1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 December 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *17,24 and 26*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

Continuation of Item 7. Claims 17, 24 and 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al. (Ann. Clin. Biochem. 2001, 38:348-355, "Yamaguchi"), in view of Watanabe et al. (J. Vet. Med. Sci., 2000, 62(7):775-778, "Watanabe"), as evidenced by Planz et al. (Journal of Virology, 1999, 73:6251-6256, "Planz") and further in view of Hatalski et al. (Journal of Virology, February 1995, 69(2):741-747, "Hatalski"), and Carbone, K.M. (Clin. Micro. Rev., 2001, 14(3):513-527, "Carbone"), for reasons of record. The claims have been amended to specifically recite the elected embodiments only.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

Applicant argues that the motivation to detect antibodies to p10 in Yamaguchi's method is not evidenced by a reference or a reasonable expectation of success. Applicant argues that the additional BDV antigen added to Yamaguchi's method might compromise the specificity of the assay unless that antigen is carefully selected by examining its expression profile and the cross reactivity of the antibody raised against the antigen. In response to Applicant's arguments, the Office is not required to provide a reference that suggests a motivation to combine teachings. The Office has provided the reasoning that the addition of p10 would increase the sensitivity of Yamaguchi's method. The reasonable expectation of success comes from the fact that Watanabe found anti-p10, anti-p24 and anti-p40 antibodies in serum at the same time (Watanabe, abstract), and that Watanabe suggests that antibodies to individual viral proteins and BDV-specific antigens are useful for establishing diagnostic methods (page 777, second column, last paragraph). As to the possibility that the additional antigen added to Yamaguchi's method might compromise specificity, the ordinary artisan would be capable of determining the parameters required to successfully perform the assay with the additional antigen.

Applicant argues that Hatalski discloses the characterization of anti-gp18 monoclonal antibodies raised specifically against gp18 protein, but not against BDV. Applicant also argues that Carbone does not teach the use of IgM antibodies to determine infection by BDV, rather IgG antibodies. Applicant notes that IgM antibodies are known to quickly disappear about one month after their appearance and are replaced by IgG. Applicant asserts that Carbone's teachings are limited to the detection of IgG during the convalescent phase. In response to Applicant's arguments, the Office understands that IgM is generally replaced by IgG, and that detection of IgG during convalescent phase is the most likely Ig to be detected at that time. However, the teachings of Carbone are being incorporated into the method of Yamaguchi. The teachings of Carbone include the disclosure that the first serological evidence of virus infection is often IgM antibody (page 516, first column, second full paragraph). Given that Hatalski demonstrates that IgM is present in response to BDV infection, and Carbone indicates that IgM is often the first serological evidence of BDV infection, one would have had a reasonable expectation of success that testing for the presence of IgM and IgG would have worked in Yamaguchi's method to increase sensitivity.

Applicant also argues that the instant specification discloses unexpected results in that it requires an unusually long period of time for the class switching from IgM to IgG to occur. Applicant notes that IgM antibodies are detected even one year after BDV infection (page 12, line 17-22). Applicant argues that without this information about the long period of time for class switching, one would not have been motivated to detect both IgM and IgG at a later phase of BDV infection. In response to Applicant's arguments, the Office notes that the claims are not limited to detection of BDV at later stages of infection. Since one cannot determine an active or past infection by detecting antibodies, one can only determine whether an infection has ever taken place. Thus, if one does not know the stage of infection, one would be motivated to increase sensitivity of Yamaguchi's assay to detect any possible markers of an infection at any stage, which includes IgM (for the earlier stage) and IgG (for later stages). Applicant's discovery that IgM is present one year after infection does not have any impact on the motivation to increase sensitivity of the assay because the claims are not limited to detection of BDV at any certain period of time. Even if the claims were limited to a particular period of time, such as a year after infection, such an embodiment would not be enabled because one cannot determine (with antibodies) when the initial infection took place.

Applicant argues that the present invention provides unexpectedly superior results over Yamaguchi's ECLIA method. In response, the Office has considered the results in Table 1, however, these results are not unexpected. The Office has already set forth the motivation to increase sensitivity of Yamaguchi's assay by detecting p10 antibodies in addition to the other antibodies. The expectation of one of ordinary skill, is that detecting p10 antibodies will increase the sensitivity of the assay, which is the result that Applicant obtained. Thus the improved sensitivity of the assay would have been expected.